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COVID-19 Vaccine Frequently Asked Questions for Healthcare Professionals

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To read the FAQ for the general public, please visit the North Dakota Department of Health (NDDoH) website.

PLEASE NOTE: This document is updated as new information becomes available.

Vaccine Development and Approval

1) Is there a vaccine that protects against COVID-19 (SARS-CoV-2)?

Yes. Currently, there are two vaccines available to prevent COVID-19. The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to permit the emergency use of the unapproved products (Pfizer-BioNTech and Moderna's COVID-19 vaccines) for active immunization to prevent COVID-19 in individuals 16 years of age and older in the United States.

Several other COVID-19 vaccines are in clinical trials but have not been approved. Johnson & Johnson (Janssen Pharmaceuticals) submitted a request for Emergency Use Authorization to the FDA on February 4, 2021. The FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC) will meet on February 26, 2021 to discuss this request. Some of the vaccines in clinical trials are currently being manufactured at the same time that clinical trials are occurring, so if approved for distribution, doses are available. If not approved, manufactured doses will be discarded.

2) When did COVID-19 vaccines become available?

The Pfizer COVID-19 vaccine and the Moderna COVID-19 vaccine both became available in December 2020. Vaccine supply is limited and vaccination is currently limited to certain priority groups.

For the most up-to-date information, please visit the NDDoH website.

A COVID-19 pipeline tracker is available online.

3) Why is the COVID-19 vaccine development timeline so condensed compared to when other vaccines are licensed?

Some of the approaches that are being employed to shorten the timeline ***without sacrificing quality and safety*** include:

- Utilizing existing technology – many of the methods for producing a COVID-19 vaccine were previously being developed and explored for other vaccines.
- Developing vaccines immediately after viral genome sequence is available.
- Financing – The federal government has provided financing for COVID-19 vaccine development.

- Manufacturing – While completing the large phase III clinical trials, manufacturers can begin producing the vaccine, so that if it is shown to be safe and effective, they will have large numbers of doses ready. This is not typical because if the vaccine does not work, the manufacturer will have spent a significant amount of money to produce something that needs to be thrown away.
- Support efforts – While waiting for a vaccine to be ready, many other aspects of vaccine delivery can be prepared, including:
    - Developing plans for how to distribute the first, limited quantities that will be available
    - Ensuring adequate supplies for distributing and administering vaccine, like vaccine vials, syringes and other equipment needed to vaccinate
    - Establishing mechanisms for distribution to large subsets of the population

A diagram explaining how the process has been shortened is available from Operation Warp Speed.

4) The development and production of a COVID-19 vaccine has been called "Operation Warp Speed", does this mean shortcuts have been taken?

Operation Warp Speed is a partnership between the United States Department of Health and Human Services, the United States Department of Defense, and the private sector. The goal of Operation Warp Speed is to accelerate the development, manufacturing, and distribution of COVID-19 vaccine.

The Food and Drug Administration (FDA) has a well outlined regulatory process that assures any licensed vaccine has gone through a rigorous process to assure that it meets a standard for safety and efficacy before being released. All COVID-19 vaccine candidates being studied in the United States are in the process of completing these rigorous studies with no compromises in the process.

What has been significantly shortened (i.e. the "warp speed") is the production process. The federal government has decided to fund the production of the leading vaccine candidates at the same time they are undergoing studies to assure their safety and efficacy. Should the vaccine candidate meet the FDA's safety and efficacy requirements, supplies would then be ready to start immunizing right away.

A summary of Operation Warp Speed's Strategy and Approach is found in the New England Journal of Medicine**.**

5) What types of COVID-19 vaccines are in clinical trials?

According to the Children's Hospital of Philadelphia's Vaccine Education Center, several approaches to COVID-19 vaccines are currently being tested. They include both tried-and-true as well as new approaches.

Here is a brief summary of these different strategies:

- Inactivated vaccine — The whole virus is killed with a chemical and used to make the vaccine. This is the same approach that is used to make the inactivated polio (shot), hepatitis A and rabies vaccines.
- Subunit vaccine — A piece of the virus that is important for immunity, like the spike protein of COVID-19, is used to make the vaccine. This is the same approach that is used to make the hepatitis B and human papillomavirus vaccines.
- Weakened, live viral vaccine — The virus is grown in the lab in cells different from those it infects in people. As the virus gets better at growing in the lab, it becomes less capable of reproducing in people. The weakened virus is then used to make the vaccine. When the weakened virus is given to people, it can reproduce enough to generate an immune response, but not enough to make the person sick. This is the same approach that is used to make the measles, mumps, rubella, chickenpox and one of the rotavirus vaccines.
- Replicating viral vector vaccine — In this case, scientists take a virus that doesn't cause disease in people (called a vector virus) and add a gene that codes for, in this case, the coronavirus spike protein. Genes are blueprints that tell cells how to make proteins. The spike protein of COVID-19 is important because it attaches the virus to cells. When the vaccine is given, the vector virus reproduces in cells and the immune system makes antibodies against its proteins, which now includes the COVID-19 spike protein. As a result, the antibodies directed against the spike protein will prevent COVID-19 from binding to cells, and, therefore, prevent infection. This is the same approach that was used to make the Ebola virus vaccine.
- Non-replicating viral vector vaccine — Similar to replicating viral vector vaccines, a gene is inserted into a vector virus, but the vector virus does not reproduce in the vaccine recipient. Although the virus can't make all of the proteins it needs to reproduce itself, it can make some proteins, including the COVID-19 spike protein. No currently licensed vaccines use this approach.
    - ***The Johnson & Johnson (Janssen Pharmaceuticals) vaccine is a non-replicating viral vector vaccine.***
- DNA vaccine — The gene that codes for the COVID-19 spike protein is inserted into a small, circular piece of DNA, called a plasmid. The plasmids are then injected as the vaccine. No currently licensed vaccines use this approach.

- mRNA vaccine — In this approach, the vaccine contains messenger RNA, called mRNA. mRNA is taken up in cells and then the cell processes it to make proteins. Once the proteins are produced, the immune system will recognize them and make a response against them to create immunity. In this case, the protein produced is the COVID-19 spike protein. No currently licensed vaccines use this approach.
    - ***The Pfizer and Moderna vaccines are both mRNA vaccines.***

For more information on the most recent updates on COVID-19 vaccines being developed, undergoing clinical trial, and approved/authorized for use, please see The New York Times Coronavirus Vaccine Tracker.

6) How does the size of COVID-19 vaccine clinical trials compare to clinical trials for other vaccines routinely used in the United States?

According to an article published in *Human Vaccines and Immunotherapeutics* in 2012, phase III clinical trials for vaccines currently being used in the United States included, on average, 29,844 participants. Ongoing phase III clinical trials for COVID-19 vaccine include or plan to include at least 30,000 participants.

Pfizer enrolled more than 43,000 individuals in their Phase III clinical trial. Moderna enrolled approximately 30,000 people in their Phase III clinical trial. Johnson & Johnson also enrolled more than 43,000 people.

7) Are people from different races and ethnicities being included in clinical trials for COVID-19 vaccines?

Yes. Vaccine manufacturers have made special effort to ensure clinical trials are inclusive of people from different races and ethnicities. Both Pfizer and Moderna reported that at least 30% of participants are from diverse backgrounds (Black, Hispanic, Asian, American Indian). Johnson & Johnson reported that 26% of participants in the U.S. and 31% of its participants globally are from diverse backgrounds.

8) What will be needed to license a COVID-19 vaccine in the United States?

Vaccine manufacturers must follow guidance provided by the FDA while developing any COVID-19 vaccine. This includes requirements to share information about how they determined that a vaccine is safe and effective. They will need to provide data for review and information, so the FDA and other scientists can understand how the studies were designed, how many people were evaluated, and how the testing to obtain the data was done. At first, COVID-19 vaccine(s) will not be fully licensed (Biological License Application) but will receive Emergency Use Authorization.

9) What is Emergency Use Authorization?

During a public health emergency, the FDA can use its Emergency Use Authorization (EUA) authority to allow the use of unapproved medical products, or unapproved uses of approved medical products, to diagnose, treat, or prevent serious or life-threatening diseases when certain criteria are met, including that there are no adequate, approved, and available alternatives. Currently available COVID-19 vaccines have been made available through EUA.

The FDA has established strict safety and efficacy criteria in order for a vaccine to be approved through EUA. Criteria includes two months post vaccination data, minimum clinical trial size, at least a 50% effectiveness and a certain number of severe COVID-19 cases in participants. COVID-19 vaccines will also be reviewed by external, independent experts.

Additional information about EUA is available on FDA's website.

10) Can you explain the difference between EUA and a Biological License Application (BLA)?

- An EUA is granted by the FDA and can be completed in a short amount of time (weeks). An EUA allows the use of unapproved medical products, or unapproved uses of approved medical products, to diagnose, treat, or prevent serious or life-threatening diseases when certain criteria are met, including that there are no adequate, approved, and available alternatives. The FDA must determine, among other things, that the ***known and potential benefits of a product outweigh its known and potential risks***.
- A BLA is also undertaken by the FDA but can take up to a year to complete. A BLA can only be approved if FDA determines there is ***substantial evidence of safety and effectiveness*** from adequate and well-controlled trials.
- Both EUAs and BLAs require data showing the vaccine is safe and effective.
- For both an EUA and a BLA, the FDA receives advisement from the Vaccine and Related Biological Products Advisory Committee (VRBPAC). VRBPAC is an external, expert committee (e.g. scientists, physicians, biostatisticians, and a consumer representative) that reviews and evaluates data concerning the safety, effectiveness and appropriate use of vaccines and related biological products.
- Because vaccines are given to millions of ***healthy*** individuals, the requirements for vaccine EUAs are ***much stricter*** than requirements for those drugs that have received EUA thus far during the COVID-19 pandemic for treatment of the ill.

11) Why did the FDA issue an EUA before a BLA for a COVID-19 vaccine?

- A vaccine for COVID-19 was first approved under EUA to promote more *rapid and widespread* deployment and administration of COVID-19 vaccine.
- A vaccine may be issued under an EUA with the *ultimate goal* of receiving a BLA.

- A vaccine issued under EUA will continue to be monitored and evaluated by multiple agencies in the United States (e.g. the Center for Disease Control and Prevention [CDC] and the FDA), to assure any vaccine authorized under EUA is safe and effective.

COVID-19 Vaccine Safety and Efficacy

12) Is the COVID-19 vaccine safety tested?

Yes. All COVID-19 vaccine candidates are being studied in large groups of people in order to ensure they are both safe and effective. After vaccines are approved for emergency use or full licensure, they will continue to be monitored for safety through the robust vaccine safety monitoring system in the U.S.

If a serious potential adverse event is noted during a clinical trial, that trial may be paused while that event is investigated. Because of high safety standards for vaccines, it's typical for most vaccine candidates to not make it to the final stages of testing. For COVID-19 vaccines in clinical trials, it is possible that not all vaccine candidates will come to market.

13) What is the current safety and efficacy of COVID-19 vaccines in clinical trials?

Pfizer, Moderna, and Johnson & Johnson have all indicated that their COVID-19 vaccines are safe and effective.

In clinical trials, Pfizer's COVID-19 vaccine showed no serious safety concerns, and there were no serious adverse events reported for Moderna's COVID-19 vaccine. Johnson & Johnson has not reported any significant safety concerns related to their COVID-19 vaccine and the vaccine was generally well-tolerated.

Pfizer reported 95% efficacy for those who received two doses, while Moderna reported 94.1% efficacy for those who received two doses. The COVID-19 vaccine made by Johnson & Johnson, which has not received FDA approval yet, was 72% effective at preventing moderate to severe COVID-19 in U.S. clinical trial participants. This vaccine is also 85% effective at preventing severe disease and it offered complete protection against COVID-19-related hospitalization and death 28 days after vaccination.

Full safety and efficacy information is available in the FDA briefing documents (Pfizer and Moderna). Information from other clinical trials will be available and reviewed before vaccines are administered.

14) What is efficacy? Is there a difference between vaccine efficacy and effectiveness?

Vaccine efficacy and vaccine effectiveness measure the proportionate reduction in cases among vaccinated persons. The term vaccine "efficacy" is used when a study is carried out under ideal

conditions, for example, during clinical trials. Vaccine "effectiveness" is used when a study is carried out under real-world conditions.

A COVID-19 vaccine with 95% efficacy means that it has the ability to *prevent* 19 out of 20 COVID-19 infections in *those who are vaccinated*. In other words, the vaccinated group experienced 95% fewer COVID-19 cases than they would have if they had not been vaccinated.

15) How does the efficacy of the Pfizer, Moderna and Johnson & Johnson vaccines compare to other vaccines?

The Pfizer, Moderna and Johnson & Johnson vaccines' efficacy is among the best we have available compared to all recommended vaccines. For example, compare the efficacy of COVID-19 vaccines to other routinely recommended vaccines:

- Pfizer novel coronavirus vaccine (2 doses): 95%
- Moderna novel coronavirus vaccine (2 doses): 94.1%
- Johnson & Johnson novel coronavirus vaccine (1 dose): 72% - U.S. Trial
- Influenza vaccine (1 dose): ~44%
- Chickenpox/varicella vaccine (2 doses): 90%
- Measles (MMR-2 doses): 97%

16) I heard the Johnson & Johnson COVID-19 vaccine has been reported to be only 66% effective. Why would I want this vaccine when Pfizer and Moderna's vaccine effectiveness is so much higher?

Johnson & Johnson has recently released some preliminary information on their COVID-19 vaccine. While we still do not know much regarding the results of their phase 3 clinical trial, what we do know is that the vaccine only requires *one dose*. Further, their vaccine has been shown to be 85% effective at preventing severe disease and it demonstrated *complete protection against COVID-19 related hospitalization and death*. This vaccine is incredibly valuable in our fight against COVID-19. Since the beginning of the pandemic we have had over 447,000 deaths from COVID-19 and the virus is the leading cause of death in the U.S. A vaccine that is highly effective at preventing severe disease and death from COVID-19 is an incredible tool to protect our community and vaccinating is the only way we can get back to normal.

17) What is the efficacy of a COVID-19 vaccine if I only receive one dose of a two-dose series?

There is very limited data on the efficacy of Pfizer's and Moderna's COVID-19 vaccines when only one dose is given. Pfizer has indicated that the efficacy of their COVID-19 vaccine after one dose is at least 52%. Moderna has noted 80.2% efficacy after one dose. For best protection, it is recommended that individuals receive two doses.

18) Why was the Johnson & Johnson clinical trial paused? Does this mean the vaccine is not safe?

In October of 2020, Johnson & Johnson announced that their COVID-19 vaccine clinical trial was paused because of an unexplained illness in a study participant. In this instance, the study paused the recruitment of new participants while the event was investigated by an independent safety monitoring board and medical experts. Based on information gathered from their investigation, Johnson & Johnson found no evidence that the vaccine caused the illness and the study resumed enrollment approximately 2 weeks later.

It is not uncommon for clinical trials to be paused. When/if a serious adverse event occurs during clinical trials, the event is reviewed by medical experts and the clinical trial is paused. Pauses in clinical trials should be reassuring to the public; pauses tell us that safety monitoring systems work and safety is a top priority.

19) Is it true that people in the COVID-19 vaccine clinical trials died?

According to data released by Pfizer and Moderna, clinical trial participants did pass away during the safety monitoring period following vaccination. Deaths occurred in participants in the vaccinated and the unvaccinated groups. However, it is important to note that the deaths that occurred in the vaccinated group were not caused by the vaccination.

In the Pfizer briefing document for Emergency Use Authorization, six deaths were noted in the study population; 2 in the vaccine group and 4 in the placebo group (placebo group = those who did not get the vaccine). In the Moderna briefing document for EUA, 13 deaths were noted; 6 in the vaccine group and 7 in the placebo.

- For those in the vaccine group, none of the deaths were related to vaccine administration.
- **The rate of deaths in the study group occurred at a similar rate to that which would be expected in the general population.**

20) How will safety of the COVID-19 vaccine be monitored?

COVID-19 vaccine safety will continue to be monitored after a vaccine is made available to the public.

- The Vaccine Adverse Events Reporting System (VAERS) will be used to identify signals that might indicate a safety issue.
- The Vaccine Safety Datalink (VSD) will also be used. VSD is an active surveillance system that monitors electronic health data for adverse events in various healthcare settings.
- The Clinical Immunization Safety Assessment Project (CISA) will conduct clinical research and assess complex vaccine safety issues.

- A new, additional safety monitoring program, V-SAFE, is also being used to monitor COVID-19 vaccines using smartphones for health surveys.
- Additional information about safety monitoring is available on CDC's COVID-19 vaccine website.

21) Is the COVID-19 vaccine being studied in children or pregnant women?

Yes. Pfizer has fully enrolled its COVID-19 vaccine trial in children ages 12-15. Results are expected in the first half of 2021. Moderna is currently enrolling children 12 and older in clinical trials.

The vaccine was not specifically studied in pregnant women. Before vaccines are studied in pregnant women, developmental and reproductive toxicity (DART) studies, which use animal models, are conducted to ensure safety of vaccines in pregnant women. Pfizer DART studies are currently underway and results are expected in the near future. Moderna's DART studies found no safety concerns in pregnant animals. Pregnant women who opt to receive the vaccine should report their pregnancy in V-SAFE to be followed for safety monitoring and pregnancy outcomes.

22) If vaccine trials do not include people with autoimmune conditions, how will we know if they can be vaccinated?

The requirements related to who can participate in a vaccine trial vary based on the company running them, the disease they are seeking to protect against, and various types of autoimmune conditions. Often the first studies are the most restrictive, so that the data are not influenced by other conditions. Later scientists and healthcare providers will accumulate data for different sub-groups. In some cases, specific trials will be conducted, but often the information on healthy adults can inform what to expect regarding different conditions. About half of the people participating in clinical trials are considered high-risk for COVID-19.

23) Do COVID-19 vaccines cause people to faint?

Fainting, also called syncope, is a common event surrounding vaccination. It is not caused by a vaccination itself; fainting is thought to be caused by the vaccination process (ex. anxiety associated with vaccination). Fainting is usually not serious and has no long-lasting effects.

Because fainting is a common occurrence for vaccinated individuals, we expect to hear reports of individuals who faint when they receive their COVID-19 vaccine. Fainting is not a sign of a vaccine reaction. To help minimize the risks associated with fainting, everyone who receives a COVID-19 vaccine is recommended to be monitored for 15 minutes following vaccination.

To see more information regarding fainting after vaccination, please visit the CDC website.

24) Can individuals with an allergy to latex receive a COVID-19 vaccine?

Yes. People with a latex allergy can receive the COVID-19 vaccine. There is no latex in the vaccine and the vaccine vial's rubber stopper does not contain latex.

It is still important to ask patients about any latex allergies so you can ensure that latex containing products (ex. gloves) are not used to care for the patient.

25) I heard reports of anaphylaxis following receipt of Moderna and Pfizer COVID-19 vaccines. Should I be concerned about an allergic response from the vaccine?

Anaphylaxis is an acute and potentially life-threatening serious allergic reaction that rarely follows vaccination. There have been some reports of anaphylaxis following receipt of COVID-19 vaccine, however, it is rare. The CDC has recently updated the estimated rates of anaphylaxis following COVID-19 vaccine administration to the following: 5 cases per million doses of Pfizer vaccine administered and 2.8 cases per million doses of Moderna vaccine administered. The CDC recommends that all individuals be monitored for at least 15 minutes following vaccination to monitor for anaphylaxis.

COVID-19 vaccines were studied thoroughly in clinical trials prior to receiving EUA. The phase 3 trial results indicated ***that vaccines were generally well tolerated with no serious safety concerns reported***. However, it is possible for vaccines to cause allergic reactions. As quoted by Dr. Paul Offit, a vaccine expert, "Certainly, vaccines can cause severe allergic reactions. In the U.S., roughly one of every 1.4 million doses of vaccines is complicated by a severe allergic reaction." The CDC advises telling a provider if you have any severe, life-threatening allergies before taking any vaccine, including the COVID-19 vaccine.

The FDA and CDC have included a history of severe allergic reactions to the COVID-19 vaccine or any COVID-19 vaccine ingredient as a reason not to receive a COVID-19 vaccine. Additionally, individuals who have had an immediate allergic reaction to COVID-19 vaccine or a COVID-19 vaccine ingredient should not receive the vaccine.

Individuals who have a history of anaphylaxis to any other vaccine or injectable therapy (e.g., intramuscular, intravenous, or subcutaneous) may receive a COVID-19 vaccination, but should be counseled about the unknown risks of developing a severe allergic reaction and balance these risks against the benefits of vaccination. They should also be monitored for 30 minutes following vaccination.

The Johnson & Johnson vaccine has not observed any cases of anaphylaxis in their clinical trial, suggesting that anaphylactic events may be extremely rare when the vaccine becomes available to the public.

The CDC has posted guidelines for managing anaphylaxis at vaccination sites here.

26) What are the FDA and CDC guidelines regarding allergic reactions and administering COVID-19 vaccine?

The FDA has included a history of severe allergic reactions to a previous dose of COVID-19 vaccine or any COVID-19 vaccine ingredient as a contraindication for the COVID-19 vaccine. Additionally, individuals who have had an immediate allergic reaction to COVID-19 vaccine or a COVID-19 vaccine ingredient should not receive the vaccine.

Because of reports of anaphylactic reactions in individuals vaccinated outside of clinical trials, additional guidance has been created. All individuals should be monitored for 15 minutes post-vaccination. The CDC has recommended persons who have had a severe allergic reaction to any vaccine or injectable therapy (intramuscular, intravenous, or subcutaneous) can receive COVID-19 vaccine, but under the following conditions:

- Individuals must be counseled about the unknown risks of developing a severe allergic reaction and balance these risks against the benefit of vaccination.
- Individuals should be observed after vaccination to monitor for the occurrence of immediate adverse reactions for 30 minutes (versus 15 minutes generally recommended following vaccination).

Individuals with other types of allergies, such as food, latex, pollen or other substances do not have to take special precautions and can receive a COVID-19 vaccine.

To see the American College of Allergy, Asthma, and Immunology's guidance on risk of allergic reaction to COVID-19 vaccine, please click here.

27) Do COVID-19 vaccines cause Bell's palsy?

At this time, Bell's palsy does not appear to be associated with COVID-19 vaccination. In the Pfizer clinical trial data, four cases of Bell's palsy were noted in the vaccine group while zero cases were noted in the placebo group. In the Moderna clinical trial data, three cases were noted in the vaccine group and one case was noted in the placebo group. **The cases in the vaccine group do not represent a frequency above the rate of Bell's palsy that is expected in the general population**. This was further substantiated with data presented at the January 27, 2021 ACIP meeting. Data from the Vaccine Safety Datalink showed no increased risk of Bell's palsy in vaccinated individuals. Surveillance for cases of Bell's palsy will continue as the vaccine is administered to the general population to determine if vaccination is associated with increased risk of Bell's palsy.

28) Do COVID-19 vaccines cause Guillain-Barré Syndrome (GBS)?

To date, no cases of Guillain-Barré Syndrome (GBS) have been reported following vaccination in the COVID-19 vaccine clinical trials. Additionally, the Advisory Committee on Immunization Practices (ACIP) shared safety data in January 2021; the data showed no association between GBS and COVID-19 vaccination. Safety monitoring systems will continue to monitor for cases of GBS to determine if vaccination is associated with onset of GBS.

29) Can patients who have previously had Guillain-Barré Syndrome (GBS) receive a COVID-19 vaccine?

Patients who have previously had GBS may receive COVID-19 vaccines. With few exceptions, the ACIP general best practice guidelines for immunization do not include a history of GBS as a precaution to vaccination with other vaccines.

Questions about Enrolling as a COVID-19 Vaccine Provider with NDDoH

30) Which healthcare providers should enroll with the NDDoH to receive COVID-19 vaccine?

Any healthcare provider who is able to vaccinate is encouraged to enroll to receive COVID-19 vaccine through the state. This includes private healthcare providers, local public health, tribal health, pharmacies, and long-term care facilities.

Some facilities are receiving COVID-19 vaccine directly from the federal government; this includes Indian Health Service (IHS), Department of Defense, and Veterans Administration. These facilities should not enroll to receive COVID-19 vaccine from the NDDoH.

31) Can healthcare providers still enroll as COVID-19 vaccine providers with NDDoH? Where can we learn more?

Enrollment for providers to receive COVID-19 vaccine is still open. Providers are encouraged to enroll as soon as possible, as vaccine will likely be available in the near future. Additional information about enrollment is available on the NDDoH COVID-19 vaccine website.

32) If our clinic has several outlying clinics, does each clinic need to enroll to become a COVID-19 vaccine provider?

Yes. Each physical site where COVID-19 vaccine will be located needs to be enrolled separately.

33) Can a vaccine be redistributed among providers within the same healthcare system?

As much as possible, vaccine will be shipped to the healthcare organization location where it will be administered to limit the possibility of storage and handling issues. Limited providers have been selected to redistribute COVID-19 vaccine within their own organizations. This includes large health systems and district local health departments.

34) Can COVID-19 vaccine be transferred to other providers?

COVID-19 vaccine can be transferred to other enrolled COVID-19 vaccine providers in an effort to avoid wastage. Transfers need to be pre-approved by the NDDoH by emailing covidvaccine@nd.gov. COVID-19 vaccine cannot be transferred to providers who have not enrolled with the NDDoH to receive COVID-19 vaccine.

35) Can a healthcare organization choose to order/stock certain COVID-19 vaccines?

No. Allocations will be based upon available COVID-19 vaccines.

Priority Groups

36) Who has been identified as priority populations?

COVID-19 vaccine supply is limited and needs to be prioritized.

At this time, the North Dakota COVID-19 vaccine priority groups have been determined in the following phases in order of priority:

Phase 1

- Phase 1A (~ 82,000 people):
    - Healthcare workers
    - First Responders
    - Long-term care residents and staff
- Phase 1B (~230,000 people):
    - Adults 75 and older
    - Adults age 65-74 with 2+ underlying conditions
    - Other congregate setting residents and staff (e.g. corrections)
    - Adults age 65-74 with 1 underlying conditions
    - People of any age with 2+ underlying conditions
    - Childcare workers
    - Preschool and K-12 school workers
- Phase 1C (~165,000 people):
    - National Guard, not previously covered

- Grocery workers
- Public safety answering points (911)
- COVID-19 vaccine manufacturing workers
- Health care/public health workers not in Phase 1A
- Public transit - including bus, taxi and ride-share - workers
- People age 16-64 with 1 underlying condition
- Blood bank workers not previously vaccinated
- IT workers unable to work from home
- All other essential workers per Cybersecurity and Infrastructure Security Agency (CISA) unable to work from home
- Veterinary professionals

Phase 2

- General Public

The federal Advisory Committee on Immunization Practices (ACIP) will make continued recommendations as to who should be prioritized for COVID-19 vaccine. To view the slides from previous ACIP meetings regarding this topic, please visit their website. Further, the North Dakota COVID-19 Vaccination Ethics Committee has developed the above priorities amongst the priority groups, as vaccine is limited. The committee determined priority groups utilizing ACIP recommendations as guidance.

Please visit the NDDoH COVID-19 vaccine website for the most up-to-date information regarding priority groups.

37) How were the priority groups for COVID-19 vaccine allocation and distribution created?

The federal Advisory Committee on Immunization Practices made recommendations regarding priorities for COVID-19 vaccination. North Dakota had to further prioritize amongst these groups due to limited vaccine supplies.

The North Dakota Advisory Committee on COVID-19 Vaccination Ethics has been tasked with providing recommendations to Unified Command for allocating doses of vaccine as they arrive in the state. The Committee is comprised of five voting members: a physician, an ethicist, a local public health representative, a representative of the Department of Human Services and a representative of the Department of Health. The committee is facilitated by a retired medical epidemiologist who is acting as advisor to the Division of Immunization. For more information on this committee please see the Advisory Committee on COVID-19 Vaccination Ethics FAQ on the NDDoH website.

The committee unanimously voted to be guided by a set of ethical principles laid out by the National Academies of Science, Engineering and Medicine in a document called Framework for

Equitable Allocation of COVID-19 Vaccination. The ethical principles can be summarized as follow:

- Achieving maximum societal benefit by optimally protecting health and socioeconomic well-being
- Ensuring that each human life is treated with equal dignity, worth and value
- Mitigating the disparities in disease impact on different populations
- Ensuring fairness and impartiality
- Acting transparently
- Making decisions based on the best available evidence

For more information on the ACIP's recommendations, please visit ACIPs' Ethical Principles for Allocating Initial Supplies of COVID-19 Vaccine - United States, 2020

38) Why was my group not considered in a higher tier in the priority groups?

Great consideration went into determining priority groups. The North Dakota Advisory Committee on COVID-19 Vaccination Ethics considers the following in determining priority:

- Risk and intensity of exposure to COVID-19
- Likelihood of adverse outcome if infected with COVID-19
- Critical role in ensuring survival of infected patients and ensuring the integrity of community function

In considering risk, many factors may fall under the above categories including living in a congregate setting, known impact of the epidemic on a population, provision of direct or indirect patient care especially to persons at increased risk or known to have COVID-19, having underlying health conditions or being age 65 or older. Separation of one group from another is often determined not just by the presence of a risk factor but by the number of factors each group has.

The committee recognizes that there is no one "right" answer, but some answers are better than others. ***Unfortunately, not everyone can be highest priority for vaccination.***

For more information on priority groups, please visit the CDC website.

39) How will healthcare providers be notified when subsequent priority groups are able to be vaccinated?

Healthcare providers will be notified by email, the NDDoH website and social media of who should be prioritized for COVID-19 vaccine. Additionally, webinars will be held to educate providers about priority groups.

Storage and Handling

40) What are the requirements for storage of the COVID-19 vaccine?

Pfizer

Pfizer's COVID-19 vaccine must be stored at -70°C. These temperatures are only maintained in ultra-low temperature freezers. The vaccine is viable at this temperature for up to six months.

If stored in its original shipping container, dry ice must be replenished within 24 hours of receipt (dry ice supplied by the federal government). Dry ice must be replenished at least every five days after that for up to 15 days total. The shipment containers should not be opened more than twice a day for more than one minute each. Specific instructions about how to unpack and manage the Pfizer shipping container are available on the NDDoH website.

Once the vaccine is thawed and put into a refrigerator, it needs to be used within five days (120 hours).

For more information on storage and handling of the Pfizer COVID-19 vaccine, please see the FDA EUA Pfizer-BioNTech *Fact Sheet for Healthcare Providers Administering Vaccine*.

Moderna

Moderna's COVID-19 vaccine must be stored at -25°C to -15°C. These temperatures can be achieved in a regular freezer. The vaccine is viable at this temperature for up to six months. Once the vaccine is thawed, it can last in the refrigerator for 30 days. It can also be kept at room temperature for up to 12 hours.

For more information on the preparation and administration of the Moderna COVID-19 vaccine, please see the CDC's *Preparation and Administration Summary*.

Johnson & Johnson

Johnson & Johnson COVID-19 vaccine can be stored at -20°C for up to 2 years by the manufacturer or distributors. Vaccine cannot be refrozen by the end-user. It can further be

stored at 2-8°C for up to 3 months. The vaccine can be held up to 6 hours within a vial or syringe at either 2°C to 8°C or room temperature (maximally 25°C) after the first puncturing of the vail. The vaccine should be discarded if not used within this time.

41) Do I need to purchase a data logger for my refrigerator/freezer?

Facilities are recommended to have a digital data logger (DDL) to continuously monitor the temperature of the vaccine. Listed below are recommendations that should be considered before purchasing one:

- An active temperature display that can be easily read by all staff from the outside of the unit, without having to open the door.
- The data logger must have functionality that does not require a computer password to access the temperature display.
- The display must remain active for temperature readings (i.e., must not have sleep mode turned on).
- Alarm for out-of-range temperatures.
- A display that shows the current temperature, as well as minimum and maximum temperatures.
- Low battery indicator.
- Accuracy of +/-1°F (+/-0.5°C).
- Detachable probe in buffered material.
- Memory storage of at least 4,000 readings (device must not rewrite over old data and must stop recording when the memory is full).
- User-programmable logging interval (or reading rate) at a maximum time interval of every 30 minutes.

42) Will providers be responsible for purchasing an ultra-cold storage unit?

At this time, the NDDoH ***does not recommend*** that providers purchase a separate ultra-cold storage unit.

If receiving the minimum package quantity of 975 doses, the ultra-frozen vaccine will arrive in a shipping container able to maintain the ultra-cold temperatures for up to 15 days. The Pfizer vaccine is stable at refrigerator temperatures for 5 days.

Additionally, the NDDoH warehouse is able to repackage the Pfizer vaccine into smaller quantities that providers can use within 5 days.

43) What happens if the diluent or the cold chain is not maintained?

Providers should call the manufacturer listed on the box for viability determination. If the dose is deemed non-viable, then the doses should be reported in the NDIIS as wasted.

44) Will shipments of COVID-19 vaccine include ancillary supplies?

Yes. COVID-19 vaccine shipments will contain the following ancillary supplies:

Pfizer

Pfizer Ancillary supplies supports administration of 1,170 doses - designed for use in adults, the kit will contain:

- Needles, 1,029 per kit (various sizes for the population served by the ordering vaccination provider)
- Syringes, 1,240 per kit
- Mixing Needles, 205 per kit
- Mixing Syringes, 205 per kit
- Alcohol prep pads, 2,900 per kit
- Diluent, 200 per kit
- Needle Card, 10 per kit
- 50 surgical masks and 25 face shields for vaccinators, per kit
- Vaccination Card, 1,200 per kit

Update 1/20/2021: FDA amended the Emergency Use Authorization to reflect the additional dose and McKesson increased the individual Pfizer ancillary kit contents from a kit that supported 975 doses to a kit supporting 1170 doses (195 vials x 6 doses = 1,170). These supplies have been added to the boxes (and noted in the above list). While the number of syringes in each ancillary box will increase to support six doses, this does not necessarily guarantee that every vial will yield six doses. Only low dead-volume syringes and/or needles will consistently ensure extraction of six doses from a single vial. If standard syringes and needles are used, there may not be sufficient volume to extract a sixth dose from a single vial.

Moderna

Moderna Ancillary supplies supports administration of 100 doses - designed for use in adults, the kit will contain:

- Needles, 105 per kit (various sizes for the population served by the ordering vaccination provider)
- Syringes, 105 per kit
- Alcohol prep pads, 210 per kit

- 4 surgical masks and 2 face shields for vaccinators, per kit
- COVID-19 vaccination record cards for vaccine recipients, 100 per kit

The NDDoH warehouse is able to repackage both vaccines into smaller quantities. If your facility is receiving less than the federal minimum shipping quantity, your facility will receive adequate ancillary supplies for the amount of vaccine received.

Vaccine Information & Presentation

45) How many doses come in each kit?

Pfizer
Pfizer's COVID-19 vaccine ships in minimum increments of 1,170 doses.

Moderna
Moderna's COVID-19 vaccine ships in minimum increments of 100 doses.

Johnson & Johnson
Johnson & Johnson's COVID-19 vaccine ships in minimum increments of 480 doses.

The NDDoH warehouse is able to redistribute both vaccines into smaller quantities. If your facility is allocated less than the minimum shipping increments, you will receive vaccine from the NDDoH warehouse.

46) Will the COVID-19 vaccines be single-dose or multi-dose vials? Do the vaccines require reconstitution (mixing)?

Pfizer
The Pfizer COVID-19 vaccine comes in a 5-dose multi-dose vial. It requires diluent and on-site mixing.

Moderna
The Moderna COVID-19 vaccine comes in a 10-dose multi-dose vial. It does not have diluent or require on-site mixing.

Johnson & Johnson
The Johnson & Johnson COVID-19 vaccine comes in a 5-dose multi-dose vial. It does not have diluent or require on-site mixing.

47) How soon after reconstitution does the Pfizer COVID-19 vaccine need to be administered?

Once vaccine is thawed, it must be diluted within 2 hours. If unable to dilute within 2 hours, store at 2°C– 8°C. You must use diluted vaccine within 6 hours (discard any unused diluted vaccine after 6 hours).

Vaccine Specifics

48) How many doses of COVID-19 vaccine are required to complete the vaccine series?

Two dose vaccine series

The Pfizer COVID-19 vaccine requires two doses separated by 21 days.

The Moderna COVID-19 vaccine requires two doses separated by 28 days.

Ideally, individuals would also receive both doses from the same facility.

If it is not feasible to adhere to the recommended interval, the second dose of Pfizer and Moderna COVID-19 vaccines may be scheduled for administration *up to 6 weeks (42 days) after the first dose*. There are currently limited data on efficacy of mRNA COVID-19 vaccines administered beyond this window. *If the second dose is administered beyond these intervals, there is no need to restart the series*.

One dose vaccines

The Johnson & Johnson COVID-19 vaccine requires one dose.

There are other COVID-19 vaccines currently in clinical trials. It is important to know which vaccine you have received and when/if you need to return for additional doses. We will update this information as more vaccines become available against COVID-19.

49) What is the COVID-19 vaccine record card included with the vaccine kit?

The purpose of the vaccination record card is to provide documentation for the patient to take with them following vaccination. NDIIS will serve as the permanent medical record and can be used to generate patient specific immunization reports.

50) Will vaccine recipients be required to show their COVID-19 vaccination record card in order to get their second dose?

No. However, all vaccine recipients should be encouraged to keep their card and show it at their follow-up vaccination appointment. Encourage patients who are vaccinated to take a picture of their immunization record card with their smartphone. Retaining the COVID-19 vaccination record card is important to ensure the second dose of vaccine is the same brand/manufacturer as the first dose received.

51) For COVID-19 vaccines that require a second dose, is it necessary to start a vaccine series over if a patient doesn't come back for a dose at the recommended time?

It is not necessary to restart the vaccine series if the second dose is given beyond the recommended interval.

52) Does the typical 4-day grace period for vaccine administration apply to the COVID-19 vaccine recommendations?

Yes. Doses of COVID-19 vaccine should be given as close to the suggested interval as possible to ensure optimal protection, but the second dose can be given as early as 4 days before the second dose is due. Doses that are inadvertently administered earlier than the grace period *should not be repeated*.

53) Are COVID-19 vaccines interchangeable?

No. In order to complete a COVID-19 vaccine series, the ACIP recommends that the second dose of the vaccine be the same brand/manufacturer as the first dose.

54) For COVID-19 vaccines requiring a second dose, should healthcare providers reserve the second dose?

No. The NDDoH will assure a supply of second doses to healthcare providers who received first doses.

Healthcare providers are encouraged to schedule patients for second doses at the time of the first dose.

55) For COVID-19 vaccines requiring a second dose, if a vaccine recipient has tested positive since their first dose of COVID-19 vaccine, should they receive their second dose?

For people who have received one dose of COVID-19 vaccine and subsequently test positive before receiving dose #2, they should complete the series as soon as they have met the minimum interval for vaccination and once they have completed their isolation period.

56) Can a COVID-19 vaccine cause you to test positive on COVID-19 viral tests?

The simple answer is no. The vaccine does not contain components nor produce components in the body that would produce a positive result in currently used diagnostic tests.

Two main tests are currently in use to detect COVID-19 in the body. An RT-PCR test, sometimes just called a PCR test, is a molecular test that looks for the genetic material of the virus itself in the nose, throat, or other areas in the respiratory tract. There are many different PCR tests, and they look for *various* genes found in SARS-CoV-2. The currently used vaccines inject just one segment of genetic material (mRNA) from the virus – the segment that codes for the spike protein. The PCR tests performed at the NDDoH lab require genetic material other than the spike protein mRNA to be present before they can be deemed positive. This means the COVID-19 vaccine's sole mRNA sequence, coding only for the spike protein, is not able to cause a positive test result via PCR by itself.

The other commonly used test is a rapid antigen test that looks for one or more proteins that make up the SARS-CoV-2 virus to determine if the person has an active infection. In North Dakota, most of the rapid antigen tests are the Abott BinaxNOW tests. These look for the SARS-CoV-2 nucleocapsid protein (NP), which is different than the spike protein that is produced after vaccination. Receipt of the Pfizer, Moderna or Johnson & Johnson COVID-19 vaccine, where your body produces the spike protein, would not cause someone to test positive using a test looking for the NP.

57) Is the COVID-19 vaccine a live vaccine?

There are currently multiple vaccine candidates in various stages of clinical trials, none of which are live vaccines.

The first two COVID-19 vaccines (Pfizer, Moderna) are not live vaccines. They are mRNA vaccines.

The Johnson & Johnson COVID-19 vaccine is a non-replicating viral vector vaccine. This vaccine uses a weakened and altered version of adenovirus 26 (Ad26) which carries genetic instructions

to our cells on how to make a harmless protein from the coronavirus which our body will recognize and build immunity to. Ad26 cannot replicate and make people sick.

Administering COVID-19 Vaccine

58) Which healthcare providers can administer COVID-19 vaccine?

The following healthcare providers are able to administer COVID-19 vaccine: physicians, nurse practitioners, physician assistants, pharmacists, pharmacy interns, pharmacy technicians, registered nurses, licensed practical nurses, level 3 CNAs, and nursing students. Some of these healthcare providers such as pharmacists, pharmacy interns and pharmacy technicians may need to have additional documented training in order to administer the vaccine.

59) Do pharmacists need physician standing orders to administer COVID-19 vaccines?

No. Per guidance from the United States Department of Health and Human Services (HHS), pharmacists are able to authorize COVID-19 vaccination on their own. However, they must have completed the practical training program of at least 20 hours that is approved by the Accreditation Council for Pharmacy Education (ACPE).

60) Can pharmacy technicians administer COVID-19 vaccines? What training is required?

Yes. Per guidance on October 20, 2020 from HHS, pharmacy technicians can provide an FDA-authorized or FDA-licensed COVID-19 vaccine. A few requirements must be met:

- The pharmacy technician must be a registered technician with the North Dakota Board of Pharmacy.
- The pharmacy technician must have a current certificate in basic cardiopulmonary resuscitation.
- The pharmacy technician must be acting under the direct supervision of a pharmacist qualified and registered to provide immunizations in North Dakota.

The technician must complete a practical training program approved by the Accreditation Council for Pharmacy Education (ACPE).

61) Does the NDDoH have any guidance for addressing COVID-19 vaccinations in long-term care facilities?

Yes. The NDDoH has developed Best Practices for addressing COVID-19 vaccinations in a Long-Term Care Facility, it can be accessed here.

62) Are providers able to charge a fee for COVID-19 vaccine administration?

Yes, healthcare providers may charge a fee to administer the vaccine. Health insurance will cover these fees. Those who are uninsured and unable to pay the administration fee cannot be turned away.

The Medicare payment rates will be $28.39 to administer single-dose vaccines. For a COVID-19 vaccine requiring a series of two or more doses, the initial dose(s) administration payment rate will be $16.94, and $28.39 for the administration of the final dose in the series. These rates will be geographically adjusted and recognize the costs involved in administering the vaccine, including the additional resources involved with required public health reporting, conducting important outreach and patient education, and spending additional time with patients answering any questions they may have about the vaccine.

Vaccine doses purchased with United States taxpayer dollars will be given to the American people at no cost. Providers that participate in the CDC COVID-19 Vaccination Program contractually agree to administer a COVID-19 vaccine regardless of an individual's ability to pay and regardless of their coverage status, and also may not seek any reimbursement, including through balance billing, from a vaccine recipient. Providers administering the vaccine to people without health insurance or whose insurance does not provide coverage of the vaccine can request reimbursement for the administration of the COVID-19 vaccine through the Provider Relief Fund

For more information on COVID-19 vaccine cost and reimbursement please visit the Centers for Medicare and Medicaid Services (CMS) website.

63) What are the billing codes for COVID-19 vaccines?

CPT codes have been created for reporting COVID-19 vaccines. These CPT codes are unique for each of two coronavirus vaccines as well as administration codes unique to each such vaccine.

91300: Pfizer COVID-19 Vaccine
91301: Moderna COVID-19 Vaccine
91303: Johnson & Johnson (Janssen Pharmaceuticals) COVID-19 Vaccine

0001A: Administration of Pfizer COVID-19 vaccine dose #1
0002A: Administration of Pfizer COVID-19 vaccine dose #2
0011A: Administration of Moderna COVID-19 vaccine dose #1
0012A: Administration of Moderna COVID-19 vaccine dose #2

0031A: Administration of Johnson & Johnson (Janssen Pharmaceuticals) COVID-19 vaccine (single dose)

Additional information about COVID-19 vaccine administration fees is available at COVID-19 Vaccine Policies & Guidance | CMS.

64) Can providers bill for an office visit when administering COVID-19 vaccine?

Yes, providers can bill for an office visit when administering COVID-19 vaccine if the visit meets the criteria for office visit coding under a recipient's plan. However, the federal intent is that patients have no out-of-pocket expenses for COVID-19 vaccine. More information will be provided in the future regarding office visit fees.

65) Can COVID-19 vaccines be administered at the same time as other vaccines?

COVID-19 vaccines should not be administered at the same time as other vaccines. There should be a 14-day interval between COVID-19 vaccine and other vaccines.

However, mRNA COVID-19 vaccines and other vaccines *may be administered* within a shorter period in situations where benefits of vaccination are deemed to outweigh the potential unknown risks of vaccine coadministration (e.g. Tdap following a wound within 14 days of COVID-19 vaccination); this should be considered on a case-by-case basis between a healthcare provider and their patient. If the 14-day interval is not met, revaccination is not recommended.

66) What are the recommendations regarding tuberculosis (TB) testing and COVID-19 vaccination?

For healthcare personnel or patients who require baseline TB testing (at onboarding or entry into facilities) at the same time they are to receive an mRNA COVID-19 vaccine:

- Perform TB symptoms screening on all healthcare personnel or patients.
- If utilizing the IGRA, draw blood for interferon gamma release assay prior to COVID-19 vaccination.
- If utilizing the TST, place prior to COVID-19 vaccination.
- If vaccination has been given and testing needs to be performed, defer TST or IGRA until 4 weeks after COVID-19 vaccine 2-dose completion.
    - All potential recipients of COVID-19 vaccination should weigh the risks and benefits of delaying TST/IGRA with their providers.

For healthcare personnel who require testing for other reasons:

- Perform TB symptom screening on all healthcare personnel

- Test for infection should be done before or at the same time as the administration of COVID-19 vaccination. If this is not possible, prioritization of test for TB infection needs to be weighed with the importance of receiving COVID-19 vaccination based on potential COVID-19 exposures and TB risk factors.
    - Healthcare personnel with high-risk conditions for TB progression should be fully evaluated as soon as possible.
    - Healthcare personnel without high-risk conditions for TB progression should proceed with contact evaluation (i.e., symptom screening, chest radiograph or other imaging, specimen for microbiologic evaluation) but delay test for TB infection (TST or IGRA) if prioritized for receiving COVID-19 vaccination.
    - All potential recipients of COVID-19 vaccination should weigh the risk and benefit of delaying TST/IGRA with their providers.

For TB Risk Assessment Tools, visit: https://www.health.nd.gov/TB/HealthcareProviders

67) What route is COVID-19 vaccine administered?

The Pfizer, Moderna, and Johnson & Johnson COVID-19 vaccines are all administered via the intramuscular (IM) route. The deltoid muscle is recommended for routine intramuscular vaccinations. The anterolateral thigh can also be used.

68) What is the appropriate anatomic site and needle length for COVID-19 vaccines?

For instruction on vaccine administration for intramuscular (IM) injections, please see the CDC's *You Call the Shots Vaccine Administration Intramuscular (IM) Injection Adults 19 years of age and older*.

69) Do we need to wait for the COVID-19 vaccine to reach room temperature before we administer it to a patient?

The vaccine needs to be thawed, but it does not need to be at room temperature.

70) How long should patients be observed after vaccination?

People should be observed for at least 15 minutes post-vaccination. People with a history of any anaphylaxis to other vaccines or injectable therapies should be observed for 30 minutes post-vaccination.

71) If there are remaining doses in the vial, can we draw more than 5 doses of the Pfizer vaccine or 10 doses of Moderna vaccine from the multi-dose vial?

At this time, given the public health emergency, FDA is advising that it is acceptable to use every full dose obtainable from each vial. However, since these are preservative free vials, it is critical to note that any further remaining liquid that does not constitute a full dose should not be administered or pooled from multiple vials to create a full dose.

72) Can COVID-19 vaccines be pre-drawn for administration?

The NDDoH ***strongly discourages*** pre-drawing vaccine. However, immunization staff may pre-draw a limited amount of vaccine in a mass-immunization clinic setting if the following conditions apply:

- Only a single type of vaccine is administered at the mass-immunization clinic setting
- Vaccine is not drawn up in advance of its arrival at the mass-vaccination clinic location
- Prefilled syringe doses are stored at temperatures appropriate for the vaccine they hold
- No more than one vial or 10 doses (whichever is greater) is drawn into syringes
- Clinic staff monitor patient flow carefully, avoid drawing up unnecessary doses, and promptly administer pre-drawn doses.

At the end of the clinic day, discard any remaining syringes prefilled by staff. Never save these syringes for another day, and never attempt to put the vaccine dose back into a vial.

Vaccine Specific Requirements:
The Pfizer COVID-19 vaccine is only viable for 6 hours following reconstitution/dilution. Please see Pfizer's Vaccine Preparation and Administration Summary for greater detail.

The Moderna COVID-19 vaccine can be stored at room temperature for 12 hours. Please see Moderna's Vaccine Preparation and Administration Summary for greater detail.

The Johnson & Johnson COVID-19 vaccine can be stored at room temperature up to 6 hours after the first puncture of the vial. More information will be available if/when the product is authorized.

73) How do I track and manage excess vaccine doses (such as a 6th Pfizer dose from a vial or an 11th Moderna dose from a vial) in NDIIS?

Providers able to use the additional dose(s) will need to make frequent adjustments to their vaccine inventory doses on hand in the NDIIS. The number of doses entered into your NDIIS inventory is based on doses per vial x the number of vials your site received. If your NDIIS

inventory is a lower number of doses on hand than the number of doses you still have because you have been able to get extra doses out of vials, you will need to adjust your inventory based on how many doses are still remaining in your storage unit. The NDDoH Division of Immunization is reporting provider vaccine inventory to Vaccine Finder daily on behalf of all enrolled providers, so it is important that provider vaccine inventory in the NDIIS is correct and current every day. You should not have a negative balance for your inventory.

The NDIIS has a report available to all active users that will show provider-level COVID-19 vaccine inventory on hand. This report can be used to see NDIIS inventory on hand and to know which lot number needs to be adjusted. There are detailed training materials on how to run the COVID-19 Provider Inventory report and how to make inventory adjustments in the NDIIS on the NDIIS training website (https://www.health.nd.gov/immunize/ndiis/trainings).

If you have COVID-19 vaccine questions, you can contact the Division of Immunization via email at covidvaccine@nd.gov or call 701-328-3386 or toll-free 800-472-2180. Questions about the NDIIS can also be emailed to NDIIS@nd.gov.

74) Do gloves need to be used when administering COVID-19 vaccine?

No. Occupational Safety and Health Administration (OSHA) regulations do not require the wearing of gloves when administering COVID-19 vaccinations, unless the person administering the vaccine is likely to come into contact with potentially infectious body fluids or has an open lesion on their hand. If a healthcare worker chooses to wear gloves, he or she must change them between each patient encounter.

75) What personal protective equipment (PPE) is recommended for immunizers and those being vaccinated?

In order to reduce the risk of exposure to SARS-CoV-2, the virus that causes COVID-19, CDC recommends that all healthcare providers administering vaccines in any setting wear a surgical face mask at all times. The NDDoH also recommends eye protection.

CDC does not recommend the use of N95 respirators when administering vaccinations by any route.

Healthcare providers should implement policies for the use of cloth face coverings by all patients age 2 years and older who can tolerate them.

Additional guidance regarding PPE and immunization is available on the NDDoH COVID-19

vaccine website.

76) Can vaccinated individuals asymptomatically transmit SARS-CoV-2?

The currently available COVID-19 vaccines are around 95% efficacious at preventing symptomatic *COVID-19*. Yet, we do not yet have evidence whether getting vaccinated *prevents asymptomatic infection and transmission*. Studies are expected in the coming months that better answer this question. It is important to note that even if the vaccine does not prevent asymptomatic COVID and only prevents symptomatic COVID, it is still extremely valuable.

77) Where can I find current information on how to protect myself and my patients when administering vaccines during the COVID-19 pandemic?

CDC has published guidelines for safe vaccine administration during the COVID-19 pandemic that will be updated as needed. These guidelines focus on reducing the risk of SARS-CoV-2 transmission while in the location where immunizations are being given and during vaccine administration and can be found on the CDC website.

IAC has assembled key resources, handouts and links related to COVID-19 and vaccination on their *Vaccination and COVID-19* page and in their *Ask the Experts section on COVID-19 and Routine Vaccination*.

The NDDoH also has guidance for PPE and COVID-19 vaccination at Vaccine Storage and Handling | Department of Health.

78) Where can I find more information and resources on Pfizer's COVID-19 vaccine?

Pfizer has created an online resource for healthcare professionals on their COVID-19 vaccine. This resource includes videos, guidelines, FAQs and checklists on vaccine. This resource can be found here.

The CDC has a number of resources regarding Pfizer's COVID-19 vaccine, they can be accessed below:

- CDC's Main Page on Pfizer COVID-19 Vaccine
- Interim Clinical Consideration for Use of COVID-19 Vaccine
- Interim Consideration: Preparing for the Potential Management of Anaphylaxis After COVID-19 Vaccination
- Pfizer COVID-19 Vaccine Standing Orders
- Pfizer COVID-19 Vaccine Preparation and Administration Summary
- Pfizer COVID-19 Vaccine Preparation: Mixing Diluent and Vaccine Poster

- Pre-Vaccination Screening Checklist

The CDC has a self-paced web-based module titled: *Pfizer-BioNTech COVID-19 Vaccine: What Healthcare Professionals Need to Know*. This learning module is estimated to take around 30 minutes and reviews a variety of important topics regarding Pfizer's COVID-19 vaccine. It can be accessed here.

For a comparison of the Pfizer and Moderna vaccines feel free to see the NDDoH *Moderna Vs Pfizer Fact Sheet* or the IAC *COVID-19 mRNA Vaccines: What Clinic Personnel Need to Know Handout*.

79) Where can I find more information and resources on Moderna's COVID-19 vaccine?

Moderna has created an online resource for healthcare professionals on their COVID-19 vaccine. This resource provides additional information, guidelines, FAQs, and resources in multiple languages. The Moderna COVID-19 vaccine website can be accessed here.

The CDC has a number of resources regarding Moderna's COVID-19 vaccine, they can be accessed below:

- CDC's Main Page on Moderna COVID-19 Vaccine
- Interim Clinical Consideration for Use of COVID-19 Vaccine
- Interim Consideration: Preparing for the Potential Management of Anaphylaxis After COVID-19 Vaccination
- Moderna COVID-19 Vaccine Standing Orders
- Moderna COVID-19 Vaccine Storage and Handling Recommendations
- Pre-Vaccination Screening Checklist

The CDC has a self-paced web-based module titled: *Moderna COVID-19 Vaccine: What Healthcare Professionals Need to Know*. This learning module is estimated to take around 30 minutes and reviews a variety of important topics regarding Moderna's COVID-19 vaccine. It can be accessed here.

For a comparison of the Pfizer and Moderna vaccines feel free to see the NDDoH *Moderna Vs Pfizer Fact Sheet* or the IAC *COVID-19 mRNA Vaccines: What Clinic Personnel Need to Know Handout*.

80) What are the most common side effects from COVID-19 vaccination?

Common side effects from vaccination include pain, swelling or redness where the shot was given, a mild fever, chills, fatigue, headache, and muscle and joint aches. These side effects were also noted in COVID-19 vaccine clinical trials. Side effects are more common after the second dose for mRNA COVID-19 vaccines.

81) Are there educational materials, like a vaccine information statement (VIS), that needs to be given to patients prior to vaccination?

In order for patients to make an informed decision regarding COVID-19 vaccination, an EUA fact sheet will be required to be given to each patient.

The FDA's EUA fact sheet for Pfizer recipients and caregivers can be accessed here.
The FDA's EUA fact sheet for Moderna recipients and caregivers can be accessed here.

The FDA's Pfizer EUA fact sheet for vaccination providers can be accessed here.
The FDA's Moderna EUA fact sheet for vaccination providers can be accessed here.

82) Are there additional tools and resources we can provide to patients following their COVID-19 vaccination?

VaxText
The CDC has developed VaxText COVID-19 Vaccination Second-Dose Reminder, a free text messaging platform that providers can offer to their patients. Patients can opt in to conveniently receive text message reminders to get their second dose of COVID-19 vaccine. VaxText offers the added benefit of reminding patients to sign up for v-safe. Simply ask vaccine recipients to text ENROLL to 1-833-VaxText (829-8398) to start getting their weekly second dose reminders.

V-SAFE
V-SAFE is a smartphone-based tool that uses text messaging and web surveys to provide personalized health check-ins after you receive a COVID-19 vaccine. Through v-safe, a patient can quickly tell CDC if they are experiencing any side effects after getting the COVID-19 vaccine. Patients can register by going to vsafe.cdc.gov.

Educational Resources and Handouts

- CDC's *Prevaccination Checklist for COVID-19 Vaccines Handout*
- CDC's *What to Expect Handout*
- CDC's *Continuing the Journey of a COVID-19 Vaccine Handout*
- CDC's *COVID-19 Vaccine Fact Sheet Handout*

- CDC's *V-SAFE Information Sheet Handout*
- CDC's *What to Expect after Getting a COVID-19 Vaccine Handout*

83) Is written consent required for COVID-19 vaccination?

No. A patient presenting for vaccination is considered consent.

84) Can COVID-19 vaccine be mandated under Emergency Use Authorization?

COVID-19 vaccine will not be mandated for all North Dakotans. The unique nature of COVID-19 vaccine being available under EUA (rather than full FDA licensure) when it will first be available is unprecedented.

The Equal Employment Opportunity Commission (EEOC) has stated that employers have the legal right to mandate employees to get a COVID-19 vaccine. Specifically, employers are entitled and required to ensure a safe workplace in which "an individual shall not pose a direct threat to the health or safety of individuals in the workplace." Requiring a COVID-19 vaccine will not violate the American Disabilities Act (ADA).

Further the EEOC has stated that "Simply requesting proof of receipt of a COVID-19 vaccination is not likely to elicit information about a disability and, therefore, is not a disability-related inquiry. However, subsequent employer questions, such as asking why an individual did not receive a vaccination, may elicit information about a disability and would be subject to the pertinent ADA standard that they be 'job-related and consistent with business necessity.'"

For more information on EEOC guidelines, please see their website.

85) Where can I find information on mandating COVID-19 vaccine under EUA written in law?

It is stated in the provision section 360bbb-3 (e)(1)(A)(ii)(III) of the Food and Cosmetic Act – 21 U.S.C. 564, "Authorization for medical products for use in emergencies," which says:

(e)Conditions of authorization

(1)Unapproved product

(A)Required conditions

With respect to the emergency use of an unapproved product, the Secretary, to the extent practicably given the applicable circumstances described in subsection (b)(1), shall for a person who carries out any activity for which the authorization is issued, establish such conditions on an authorization under this section as the Secretary finds necessary or appropriate to protect the public health, including the following:

(ii)Appropriate conditions designed to ensure that individuals to whom the product is administered are informed -

(III)***of the option to accept or refuse administration of the product***, of the consequences, if any, of refusing administration of the product, and of the alternatives to the product that are available and of their benefits and risk.

Additional information about COVID-19 vaccine is available on CDC's COVID-19 vaccine website.

86) Is North Dakota a pilot state for COVID-19 vaccine?

North Dakota was one of five sites selected to participate as a planning pilot site for COVID-19 vaccine distribution. North Dakota was able to assist federal partners in planning for when COVID-19 vaccine will eventually be available. Planning topics included vaccine storage and handling, distribution, communications, information technology, data, etc. The Tribes and other partners, including pharmacies, were included in this planning process to ensure that they were able to provide valuable insight into COVID-19 vaccine planning and eventual distribution and administration.

North Dakota will ***NOT*** receive COVID-19 vaccine before other states.

Additional information about COVID-19 vaccine is available on CDC's COVID-19 vaccine website.

87) Will people who are vaccinated need to continue to wear PPE, practice social distancing, and observe quarantine recommendations?

Yes. Until a significant proportion of the population is immunized, mitigation strategies, such as mask-wearing and social distancing, will still be required.

Recent CDC recommendations have stated that vaccinated persons with an exposure to someone with suspected or confirmed COVID-19 are not required to quarantine if they meet the following criteria:

- Are fully vaccinated (e.g. ≥2 weeks following receipt of the second dose in a 2-dose series, or ≥2 weeks following receipt of one dose of a single-dose COVID-19 vaccine)
- Are within 3 months following receipt of the last dose in the series
- Have remained asymptomatic since the current COVID-19 exposure

Persons who do not meet all three of the above criteria should continue to follow current quarantine guidance after exposure to someone with suspected or confirmed COVID-19. Fully vaccinated persons who do not quarantine should still watch for symptoms of COVID-19 for 14 days following an exposure. If they experience symptoms, they should be clinically evaluated for COVID-19, including SARS-CoV-2 testing, if indicated.

88) Why do we have to continue to wear PPE and practice social distancing following a COVID-19 vaccination?

Vaccinations teach the body to successfully recognize and fight a virus without actually getting sick. Public health measures such as social distancing and mask wearing and donning PPE help to *decrease exposure to the virus*. To effectively contain this pandemic, vaccinating campaigns AND reducing exposure to the virus must continue.

We must persist to use public health measures following vaccination for the following reasons:

- ***Vaccination does not provide immediate immunity***. Both the Pfizer and Moderna vaccines require two doses, weeks apart. Depending on the vaccine, it can take four to six weeks from a vaccine's initial dose to achieve immunity and protection from the virus. During this time, it is still possible to contract an infection and fall ill.
- ***We don't yet know whether vaccines prevent transmission of COVID-19.*** The Moderna and Pfizer vaccines have shown to prevent symptomatic and severe COVID-19 infections remarkably well, but we still do not have enough data to make conclusions regarding their effectiveness at preventing asymptomatic infections. Asymptomatic carriers may not show symptoms, but speaking, breathing, and sneezing can still potentially transmit the virus to others. Future studies will have to evaluate whether vaccination decreases viral transmission before the role of public health measures are re-evaluated.
- ***We don't know how much protection COVID-19 vaccines will provide under real-life conditions.*** While the Moderna and Pfizer vaccines efficacy in clinical trial put them among the very best vaccines we have available to us, we have yet to determine how effective the vaccines will be in real-life. Under the controlled and ideal setting of the clinical trial, both vaccines were found to be ~95% efficacious, but real-world factors (e.g. how vaccine is stored, transported, administered) doesn't mimic a controlled clinical trial.
- ***The herd immunity threshold for COVID-19 is unknown.*** It is still uncertain when enough of Americans will be vaccinated to reach a threshold of protection, also known as herd immunity. The more transmissible a pathogen is, the more people must become immune in order to stop it. The percentage of the population requiring immunization to acquire herd immunity against COVID-19 is not entirely known, but is estimated to be between 70-90%.
- ***It will be impossible to know who is and isn't vaccinated in your community.*** Vaccine is being allocated in a phased approach, and although you may want to get vaccinated, your priority group may not be able to get vaccinated right away. It is going to take time for vaccine to be distributed and enough of the population to be vaccinated to reach potential herd immunity.

- ***We don't know the duration of vaccine protection.*** Information regarding the length of protection from Pfizer and Moderna vaccines are still being studied.

COVID-19 Vaccine Administration Errors

COVID-19 vaccination providers are required to report all vaccine administration errors, even those not associated with an adverse event or that may not require revaccination, to the Vaccine Adverse Event Reporting System (VAERS). To file an electronic report, please see the VAERS website. Please complete a VAERS report as soon as possible.

89) If a patient receives an invalid dose of COVID-19 vaccine, when can they receive their next dose?

If an invalid dose of COVID-19 vaccine is administered, revaccination can occur as soon as possible.

90) If a COVID-19 vaccine was administered at an incorrect site (ex. the gluteal muscle instead of the deltoid), should the dose be readministered?

At this time, the CDC does not recommend that doses given at the incorrect anatomical site be readministered. The vaccine recipient may receive the second dose (at the appropriate injection site) per the recommended vaccine schedule.

91) If a vaccine recipient moved during administration and did not receive an entire dose, is there a waiting period before the dose can be repeated or can it be given immediately?

When the vaccine recipient moves and a partial dose is administered, it is up to the professional judgement of the person administering the vaccine whether or not to readminister that dose.

- If they think most of the dose was not administered, then revaccination would be warranted and revaccination can occur *as soon as possible*; the initial dose would be considered an invalid dose.
- If they think most of the dose was given then that dose can be considered a valid dose.

The final dose (i.e., the second valid dose) should be spaced from the first VALID dose by the recommended interval.

92) For COVID-19 vaccines requiring a second dose, what if a patient inadvertently completed their COVID-19 vaccines series with two different mRNA vaccine products? (i.e. Pfizer for dose one and Moderna for dose two)

No additional doses of either vaccine are recommended at this time.

93) If some of the vaccine leaked out of the injection site, do we need to revaccinate the patient?

If it appears that only some of the vaccine was administered and some of it leaked out of the injection site, it is up to the professional judgement of the person administering the vaccine whether or not to readminister that dose.

- If they think most of the dose leaked out of the injection site, then revaccination would be warranted and revaccination can occur as soon as possible; the initial dose would be considered an invalid dose.
- If they think most of the dose remained in the injection site then that dose can be considered a valid dose.

94) Our clinic accidentally vaccinated a 17-year-old with Moderna's COVID-19 vaccine. Should the patient receive their second dose?

A 17-year old individual who inadvertently received the Moderna COVID-19 vaccine may receive the second dose if clinical decision making determines that the risk-benefit ratio favors administration of the second Moderna COVID-19 dose 28 days or more following the first Moderna COVID-19 vaccine dose.

Who Should and Shouldn't Be Vaccinated

95) What are the contraindications for the COVID-19 vaccines?

Do not administer COVID-19 vaccine to individuals with a known history of a severe allergic reaction (e.g. anaphylaxis) or immediate allergic reaction to a previous COVID-19 vaccine dose or any component of a COVID-19 vaccine.

96) Can people with underlying conditions receive the vaccine?

Yes. People with underlying conditions are at a higher risk for severe COVID-19 disease. Vaccine may be administered to these individuals who have no contraindications to vaccination. Phase 2 and phase 3 clinical trials demonstrated similar safety and efficacy profiles in persons with underlying medical conditions, including those that place them at increased risk for severe COVID-19.

97) Can people who are immunocompromised receive COVID-19 vaccine?

Yes. These individuals may be at increased risk for severe COVID-19. They may receive COVID-19 vaccine unless otherwise indicated.

Individuals should be counseled about: 1) unknown vaccine safety and efficacy profiles in immunocompromised persons, 2) potential for reduced immune responses, and 3) need to continue to follow all current guidance to protect themselves against COVID-19.

98) Can individuals with an acute illness be vaccinated? (e.g. common cold, shingles)

The presence of a moderate or severe acute illness with or without a fever is a precaution to administration of all vaccines. The NDDoH recommends that individuals consult with their healthcare provider if they are experiencing an acute illness and would like to be vaccinated. In these situations, healthcare providers should consider the risks and benefits of vaccination.

The decision to administer or delay vaccination because of a current or recent acute illness depends on the severity of symptoms and etiology of the condition. The safety and efficacy of vaccinating persons who have mild illnesses have been documented. Vaccination should be deferred for persons with a moderate or severe acute illness. After they are screened for contraindications, persons with moderate or severe acute illness should be vaccinated as soon as the acute illness has improved.

Additionally, individuals with shingles should not receive the vaccine at an anatomical site where there is an active rash.

99) Can people who have had COVID-19 receive the COVID-19 vaccine?

Yes. Vaccination should be offered to all eligible individuals, regardless of their history of prior symptomatic or asymptomatic SARS-CoV-2 infection.

There is not a minimum interval between infection and vaccination. However, current evidence suggests reinfection is uncommon in the 90 days after initial infection. Thus, **while vaccine supply remains limited**, persons with recent, documented acute SARS-CoV-2 infection may choose to temporarily delay vaccination, if desired.

Since supplies of COVID-19 vaccine are limited, healthcare providers may choose to prioritize those who previously had COVID-19 at a lower priority.

Viral testing to assess for acute SARS-CoV-2 infection or serologic testing for prior infection for the purpose of vaccine decision-making *is not recommended.*

100) Should people who have had a known previous COVID-19 infection receive a single dose of a COVID-19 mRNA vaccine versus completing the two-dose series?

A recent study has shown that the antibody response to the first vaccine dose in individuals with pre-existing immunity is equal to or even exceeds the titers found in naive individuals after the second dose. But at this time, there are no recommendations related to giving a single dose of COVID-19 vaccine to those who have recovered from a known COVID-19 infection. Those who are able and qualified for COVID-19 vaccination and have received a first dose should complete the vaccine series, regardless of a previous COVID-19 infection. The NDDoH will keep healthcare providers updated on any changes regarding COVID-19 vaccine recommendations.

101) Should people who currently have active infection with SARS-CoV-2 be vaccinated?

Vaccination should be deferred until the person has recovered from acute illness and criteria have been met to discontinue isolation.

There is not a minimum interval between infection and vaccination. However, current evidence suggests reinfection is uncommon in the 90 days after initial infection, and thus, persons with documented acute infection in the preceding 90 days may defer vaccination until the end of this period, if desired.

102) Should people who are currently in quarantine present for vaccination?

No. People who are quarantined because of exposure to COVID-19 should wait to be vaccinated until their quarantine period has ended. This is to prevent spread to COVID-19 vaccinators.

Congregate settings, including long-term care settings, homeless shelters, and correctional facilities should consider vaccination even if residents/staff are in quarantine.

103) Should individuals who have previously received passive antibody therapy for COVID-19 be vaccinated?

Vaccination should be deferred for at least 90 days to avoid interference of the treatment with vaccine-induced immune responses.

104) A patient recently tested positive for SARS-CoV-2. Should healthcare providers recommend monoclonal antibody treatment to help prevent severe disease? If recommended, the patient will not be able to be vaccinated for at least 90 days. Is that ok?

Patients at an increased risk for severe disease should be recommended to receive monoclonal antibody treatment. **It may save a patient's life**. These patients will need to wait 90 days to receive the vaccine, but until that interval is met, it is very unlikely that they will become reinfected with the virus.

105) A patient has tested positive for SARS-CoV-2 after they have received their first dose of COVID-19 vaccine of a two-dose series. Should they be given monoclonal antibody treatment to help prevent severe disease?

Yes, this treatment can be given at the provider's discretion. The CDC recommendations state that for vaccinated persons who subsequently develop COVID-19, prior receipt of an mRNA COVID-19 vaccine *should not affect treatment decision or timing of such treatment*. There is no waiting period required for administering monoclonal antibody treatment following a COVID-19 vaccine. Administering this treatment more than 10-14 days after vaccination may have limited benefit but it is still recommended.

106) A patient previously tested positive for SARS-CoV-2. This patient has received the first dose of their COVID-19 vaccine that requires two doses, and has now tested positive again. This patient is a candidate for antibody treatment. If they receive antibody treatment, when should they get their second dose of COVID-19 vaccine?

The second dose should be deferred for at least 90 days following receipt of antibody therapy.

107) Does antibody treatment impact vaccine efficacy? Does a patient who has received antibody therapy need to restart the COVID-19 vaccine series?

At this time, it is unknown how antibody treatments will impact COVID-19 vaccine efficacy.

Patients who have received one dose of COVID-19 vaccine, followed by monoclonal antibody therapy, do not need to restart the vaccine series which requires 2 doses to complete the series. These patients should receive their second dose of the vaccine once the 90-day interval has been met.

108) Can pregnant women receive COVID-19 vaccine?

Yes. Pregnant women may choose to be vaccinated. They should weigh the risk of COVID-19 with the risks of vaccination. Pregnant women should discuss vaccination with their healthcare provider.

The American College of Obstetrics and Gynecology has published guidance here. The NDDoH has compiled information on COVID-19 vaccine and pregnancy here. The CDC and World Health Organization (WHO) have aligned their recommendations for receipt of Pfizer and Moderna vaccines during pregnancy and have advised that "*based on what we know about this kind of vaccine, we don't have any specific reason to believe there will be specific risks that would outweigh the benefits of vaccination for pregnant women.*"

Considerations for vaccination include: 1) level of COVID-19 community transmission, 2) her personal risk of contracting COVID-19, 3) the risks of COVID-19 to her and potential risks to the fetus, 4) the efficacy of the vaccine, 5) the known side effects of the vaccine, 6) the lack of data about the vaccine during pregnancy.

Pregnant women who experience a fever following vaccination should be counseled to take acetaminophen, as fever has been associated with adverse pregnancy outcomes.

109) Can women who are breastfeeding receive COVID-19 vaccine?

Yes. Women who are breastfeeding may choose to be vaccinated. mRNA vaccines are not considered live virus vaccines and are not thought to be a risk to the breastfeeding infant. However, there are no data on the safety of COVID-19 vaccines in lactating women or the effects of mRNA vaccines on the breastfed infant or milk production/excretion. The American College of Obstetrics and Gynecology has published guidance here.

110) If a patient is eligible for COVID-19 vaccination but also has other vaccinations due, which vaccines should we give first?

Patients and providers should weigh the risks and benefits of different vaccines on a case-by-case basis. (e.g. If a patient has had COVID-19 in the last 90 days, it might be best to defer COVID vaccination and administer other vaccines to the patient.) Providers and patients should determine which vaccines are recommended for the patient and what the patient's current risk of contracting each disease is. If a patient has impending international travel which will put them at risk for diseases which are vaccine-preventable, they may want to consider receiving travel vaccines. Similarly, if a patient is a healthcare worker but also due for their annual influenza

vaccine, COVID-19 may present a more significant risk and they may want to consider receiving the COVID-19 vaccine first.

111) Should individuals who have received dermal fillers be vaccinated?

Infrequently, persons who have received dermal fillers may develop swelling at or near the site of filler injection (usually face or lips) following administration of a dose of an mRNA COVID-19 vaccine. This appears to be temporary and can resolve with medical treatment, including corticosteroid therapy. mRNA COVID-19 vaccines may be administered to persons who have received injectable dermal fillers who have no contraindications to vaccination. No additional precautions are needed. However, these persons should be advised to contact their healthcare provider for evaluation if they develop swelling at or near the site of dermal filler following vaccination.

112) Can children be vaccinated against COVID-19?

Pfizer's COVID-19 vaccine has been recommended for adolescents 16 and 17 years of age. Emergency Use Authorization of the Pfizer vaccine does not include use in individuals younger than 16 years of age.

Moderna's COVID-19 vaccine is only approved for individuals 18 years and older.

113) If a patient is from another state, should they receive a COVID-19 vaccine in North Dakota?

Yes. The NDDoH suggests that this should be decided on a case by case basis. Patients *can* receive a COVID-19 vaccine in ND, even if they are not a resident, if they meet certain criteria, including (but not limited to):

- Their place of employment is in ND
- Their primary care provider is located in ND
- They have a secondary residence in ND
- They are a student at a ND school, college, or university

Availability should also be dependent on whether or not the patient's priority group is currently eligible for COVID-19 vaccine under North Dakota's priorities. Please visit the NDDoH website for the latest updates on priority groups.

114) How should our health system address staff members that refuse COVID-19 vaccination?

If a staff member refuses to vaccinate, it is important to provide them with information regarding the risks associated with COVID-19 infections and the risks and benefits of COVID-19 vaccination. Additionally, consider asking them what concerns or questions they have about the

vaccine and respectfully address each concern/question. There are patient concerns below that may arise regarding the COVID-19 vaccine with suggested responses.

If a staff member still refuses after their concerns and questions have been addressed, the NDDoH has created a Declination of COVID-19 Vaccination for your use. Feel free to use this optional form. Facilities may change and/or add your own logo.

115) How should we address patients' questions regarding winter travel and COVID-19 vaccine?

Recommendations for travelers prior to first dose of COVID-19 vaccine:
Vaccines are being administered by priority groups. If your patient is a seasonal traveler or "snowbird", advise the patient they may be able to be vaccinated when vaccine becomes available to their priority group in the location they are residing. However, it is important to note that the state of their winter residence may have different priority groups for COVID-19 vaccination than North Dakota, and their ability to be vaccinated may not be the same in the state of their destination. The NDDoH encourages providers to suggest that their patients check with local health departments for COVID-19 vaccine priority groups/instructions.

Recommendations for travelers after their first dose but before their second dose of COVID-19 vaccine:
Ideally, individuals should receive their second doses from the same healthcare providers who administered the first dose. If a patient has received their first dose of COVID-19 vaccine in North Dakota and has traveled south prior to receiving their second dose of vaccine, advise them that they *may be able* to receive their second dose in that state. However, it is important to note that the state of their winter residence may have different priority groups for COVID-19 vaccination than North Dakota, and their ability to be vaccinated may not be the same in the state of their destination. If they have traveled to a winter home between doses, the NDDoH encourages providers to advise patients to check with local health departments for instructions. Further, it is important to advise patients to keep their Vaccination Record Card with them. The Vaccination Record Card will include important information on a patient's first dose of COVID-19 vaccine including which vaccine they received, when they received it, and where they received it.

116) If a patient has received their first dose of COVID-19 vaccine in a state of their winter residence and is now home (e.g. back in North Dakota) and requesting their second dose, should we provide it?

Yes. Patients that have received their first dose in a different state and are now back in North Dakota prior to receiving their second dose, should be provided COVID-19 vaccine. NDDoH

suggests using allocated "first doses" you receive for patients that classify under this group and to plan accordingly.

Vaccine Reporting

117) What are the reporting requirements?

All doses of COVID-19 vaccine will need to be reported to the North Dakota Immunization Information System (NDIIS) within 24 hours of administration. This includes doses that are entered via manual data entry into NDIIS, those that are electronically sent through an Electronic Health Record (EHR) system or through another mechanism. For more information on NDIIS, please see the NDDoH website.

118) Where do I report COVID-19 administration data?

PrepMod

PrepMod is available for all North Dakota healthcare providers to use during mass vaccination clinics.

PrepMod allows for members of the public to preregister for COVID-19 vaccine online. This will include electronic registration, consent to vaccination, consent to receive immunization reminders via text message, review the Vaccine Information Statement (VIS) or other fact sheet, report their high risk/priority group and to find the vaccination clinic nearest to them. Healthcare providers using PrepMod will be able to set up clinics and control the appointment times and number of patients per appointment to allow for social distancing. PrepMod will also document all required fields for vaccine administration then report to the NDIIS in real-time. This system will allow for a paperless vaccination clinic and no waiting in the clinic to complete forms. PrepMod will be made available to any healthcare provider in ND who would like to use it for vaccination clinics, not just COVID vaccination.

EHR

With the adoption of electronic health records (EHRs) by many health systems, data from the EHR can automatically document the vaccine record in NDIIS in real time.

119) How quickly does COVID-19 vaccine administration data need to be reported to NDIIS?

The NDDoH requires that vaccination providers enrolled in COVID-19 Vaccination Program report each dose administered within 24 hours of administration to the NDIIS.

120) Where do we report adverse reactions/effects from the COVID-19 vaccine?

NDDoH strongly encourages physicians and other providers to report all moderate and severe vaccine adverse reactions to the Vaccine Adverse Event Reporting System. Any serious adverse reaction should be reported to the NDDoH Immunization Program immediately, which would notify CDC.

Vaccine Adverse Event Reporting System (VAERS)

VAERS is a national vaccine safety surveillance program co-sponsored by the FDA and the CDC. The purpose of VAERS is to detect possible signals of adverse events associated with vaccines. VAERS collects and analyzes information from reports of adverse events that occur after the administration of vaccines in the United States. Reports can be made by healthcare professionals, vaccine manufacturers, and the public. More information on VAERS can be found on the HHS website.

For spontaneous adverse events reporting to VAERS for populations served by IHS and Tribal facilities, more information can be found on the IHS website.

V-SAFE (Vaccine safety assessment for essential workers)

V-SAFE is a new smartphone-based, after-vaccination health checker for people who received COVID-19 vaccines. The system will also provide telephone follow up to anyone who reports medically significant adverse events. A VAERS report will be taken during telephone follow-up if appropriate.

More information on registering for and step-by-step instructions on using V-SAFE please visit the CDC website.

Need help with V-SAFE?
Call 800-CDC-INFO (800-232-4636) TTY 888-232-6348
Open 24 hours, 7 days a week

National Healthcare Safety Network (NHSN)

An acute-care and long-term care facility monitoring system that will promote reporting the VAERS. See more information on NHSN on the CDC website.

121) Will vaccination rates be posted by priority groups? (ex. Vaccination rates for healthcare workers, long-term care residents, or teachers)

No. Vaccination rates are not available by priority group or profession. It is unlikely the NDDoH will be able to provide vaccination rates by priority groups, as this information is not reported through the NDIIS.

122) What is required of COVID-19 enrolled vaccine providers regarding the North Dakota COVID-19 Vaccine Locator?

North Dakota's COVID-19 vaccine locator helps members of the general public see which North Dakota provider sites have enrolled to receive and administer COVID-19 vaccine, where COVID-19 vaccine is currently available, which priority group enrolled provider sites are currently vaccinating, and how they can contact their local provider and/or express interest in receiving COVID-19 vaccine. The North Dakota COVID-19 vaccine locator can be accessed here.

This tool will be updated *daily*. All enrolled provider sites MUST MAKE SURE their NDIIS vaccine inventory is accurate by reviewing doses on hand daily. See the NDIIS training website for tip sheets and training videos on how to run the COVID-19 Provider Inventory report and how to view/adjust your inventory doses on hand.

Further, the NDDoH Division of Immunizations has developed a survey for providers to indicate which priority group they are currently vaccinating and to provide any instructions for their patients and members of their community for contracting the provider and/or expressing interest in receiving COVID-19 vaccine. This survey must be filled out at EVERY enrolled provider site. Moving forward, the survey link will be available on the NDDoH COVID-19 Vaccine Healthcare Provider resource website. ***Providers will need to submit a new survey response as they move to the next priority group and if <u>any</u> of the instructions change for the general public*** (e.g. updating instructions that the vaccines "available" are only for second doses). The survey can be found here.

123) Where can I see how many doses of COVID-19 vaccine have been administered in North Dakota?

The NDDoH COVID-19 Vaccine Dashboard provides updated information on COVID-19 vaccine doses administered, doses received, and coverage rates. This dashboard can be accessed here.

<u>Addressing patient concerns about COVID-19 vaccine</u>

As healthcare professionals, you are a patient's most trusted source for vaccine information. You will play a critical role in helping to build confidence in COVID-19 vaccination. Below are some questions and potential responses to patient concerns about COVID-19 vaccine.

124) "Should I be worried about it being a new vaccine?"

It is understandable to have questions about a new vaccine. COVID-19 vaccine development is unlike any vaccine development process in the past. Although the vaccine was created faster than any vaccine before, safety and effectiveness was paramount every step of the way. The timeline for vaccine development was shortened because certain steps in a typical vaccine development and manufacturing process occurred at the same time. Further, the FDA has strict guidelines for ***any vaccine*** authorized by EUA. They established clear and rigorous recommendations on vaccine performance and safety. Further, expert committees (VRBPAC and ACIP) will analyze the data from clinical trials to affirm vaccine safety and effectiveness prior to any EUA being granted. We have seen this process in action for the authorization of both the Pfizer and Moderna COVID-19 vaccines. In addition, the FDA is committed to engaging in continuous monitoring of COVID-19 vaccines to ensure they are ***safe*** and ***effective***.

125) "I want the vaccine, but I just don't want to be the first to get it."

Tens of thousands of people participated in COVID-19 vaccine clinical trials to help determine the safety and efficacy of the vaccines. Getting vaccinated against COVID-19 not only protects you, but also protects your loved ones and those in your community most vulnerable to the virus. Further, the clinical trial data from both Pfizer and Moderna have shown their vaccines to be around 95% efficacious, far above the FDA's goals of 50% efficacy. As Dr. Paul Offit has said, "The choice not to get a COVID-19 vaccine is the choice to be among the now [468,000] people who have died from this virus". Not getting vaccinated is the radical choice. ***The benefits of vaccinating against COVID-19 far outweigh the risks***. We will rely on everyone to get the vaccine to reach herd immunity and end this pandemic.

126) "I want to see long-term safety data before I get the vaccine."

It is understandable to want to see long-term safety data before getting vaccinated, but this is not something that is currently available. Thousands of people are dying each week, and getting vaccinated is the only way to prevent COVID-19. What we do know is that COVID-19 vaccines appear to be safe and effective.

Although a vaccine was developed quickly, vaccine sponsors and the federal government will continue to monitor the vaccines and assure they are safe and effective. Some steps of development are proceeding at the same time. Manufacturing of the vaccine occurred during the trial period before data on safety was available, while this increased the financial risk, it did not increase the product risk.

Further, Pfizer, Moderna and Johnson & Johnson had ***large*** Phase III clinical trial sizes ranging from 30,000 to 44,000 participants. The size of these trials helped to establish the ***validity*** and ***safety*** of the vaccines being tested. Further, the current vaccine safety monitoring system is strong and robust, with the capacity to effectively monitor COVID-19 vaccine safety in almost real-time. And any vaccine authorized for use will be reviewed by expert committees (VRBPAC and ACIP) prior to an EUA being issued in the United States

127) "If one product has slightly higher efficacy than another vaccine, isn't it better to get the vaccine with higher efficacy?"

Any COVID-19 vaccine that is authorized for use in the United States has met the FDA's rigorous guidelines regarding EUA and has been reviewed by both VRBPAC and the ACIP (expert committees that provide recommendations and guidance on immunizations). In the last year, we have had approximately 468,000 deaths associated to COVID-19 in the United States. While preventive measures like social distancing and masks help to slow the spread, ***the only truly preventive measure against this virus is to vaccinate.***

Both the Pfizer and Moderna COVID-19 vaccines have reported efficacy ***around 95%***, rivalling the effectiveness of some of the best vaccines available to us against other viruses such as MMR (97% effective) and chickenpox (92% effective) vaccines.

Preliminary data on the Johnson & Johnson COVID-19 vaccine has been shown to be 85% effective at preventing severe disease and it demonstrated complete protection against COVID-19 related hospitalization and death. This vaccine is incredibly valuable in our fight against COVID-19.

Further, COVID-19 vaccine supply **is extremely limited** and there are many who are waiting for their turn to get vaccinated. If you are given the opportunity to receive a COVID-19 vaccine, it means that your priority group has been deemed eligible for a highly efficacious vaccine. It is important for everyone to be vaccinated when it is their turn so we can return to normal sooner.

128) "Is the Pfizer vaccine better than the Moderna vaccine for older patients?"

Clinical trial data for both Pfizer and Moderna showed strong vaccine efficacy for older populations. Elderly individuals should not delay vaccination because of product preference. Any vaccine that has been approved for use in the United States has met FDA standards for safety and efficacy. Further, vaccine supply is extremely limited and people may not be able to choose which vaccine they would like to receive.

129) "I don't need a COVID-19 vaccine, the disease isn't that serious and we should just let it spread through the community."

The COVID-19 pandemic has had a significant impact on all of our lives. Although you may not know anyone who has been directly affected by the disease, it is ever-present in our community and now the leading cause of death in our country. Since the beginning of the pandemic, there have been over 27 million documented cases of and over 468,000 deaths attributed to COVID-19 in the United States. Getting vaccinated not only protects you but protects others you care about. By vaccinating you help to prevent the spread of disease to your friends, loved ones, and those in your community.

Further, it is not clear whether those who have cleared infection with COVID-19 virus are immune to future infection. Even if infection created long-lasting immunity, over 70% of the population (over 200 million people) would have to recover from COVID-19 to halt the epidemic. This would create a burden on our healthcare system and lead to many serious complications and millions of deaths.

130) "Why should I get a COVID-19 vaccine?"

The COVID-19 pandemic has had a significant impact on all of our lives. Although you may not know anyone who has been directly affected by the disease, it is ever-present in our community. Further, more than 1 in a 550 North Dakotans have died from COVID-19. While preventative measures like social distancing and masks help to slow the spread, *the only truly preventive measure against this virus is to vaccinate*.

By vaccinating against COVID-19, you not only protect yourself, but also prevent spread of the disease to your friends, loved ones, and those in your community. COVID-19 can have serious, life threatening complications and there is no way to know how the virus will affect you. COVID-19 vaccines are being carefully evaluated and will be authorized only if they are found to be safe and make it substantially less likely you'll get COVID-19.

For more information on the benefits of getting a COVID-19 vaccine, please see the CDC website.

131) "The new COVID-19 mRNA vaccine will literally alter your DNA, so you essentially become a genetically modified human being."

This is false. While the mRNA vaccines are the first of their kind, ***they cannot alter DNA***. The mRNA vaccines work by introducing a messenger RNA molecule into your body, which causes

cells to produce a protein that resembles one of the viral proteins that make up SARS-CoV-2. Your immune system recognizes the viral protein and generates an immune response against it.

The mRNA vaccines are unable to change your genetic makeup because the mRNA injected into the tissue to stimulate an immune response ***do not integrate into the cell nucleus of its recipients, thus genetic modification is not possible***. It only presents the body with the instruction to build a protein, which builds immunity. When the cells divide, they will only include your natural DNA. Further, the time RNA survives in the cells is relatively brief, usually only a span of hours.

The CDC has produced a handout on mRNA vaccines for healthcare professionals, this resources provides useful information on mRNA vaccines and discusses how to talk to patients with questions about this vaccine platform. The *Learn More about the New mRNA COVID-19 Vaccines* handout can be found here.

132) "I have heard COVID-19 vaccine manufacturers are not liable for vaccine injury. What happens if I have a vaccine injury?"

Serious adverse events from vaccination are extremely rare. In the event of a serious injury following vaccination with COVID-19 vaccine, the PREP Act provides immunity from liability to the vaccine manufacturer, and the Countermeasures Injury Compensation Program (CICP) provides benefits to individuals who sustained the injury. More information on the PREP Act and CICP is below.

To encourage expedient development of medical countermeasures during a public health crisis, the PREP Act was created in 2005. The PREP Act authorizes the Secretary of the Department of Health and Human Services (HHS) to issue a PREP Act Declaration that provides immunity from liability for any loss caused, arising out of, relating to, or resulting from administration or use of countermeasures to diseases, threats and conditions determined in the Declaration to constitute a present or credible risk of a future public health emergency. Previous PREP Act declarations have been issued numerous times, including those for the H1H1 pandemic in 2009.

The PREP Act does provide manufacturers of countermeasures (i.e. COVID-19 vaccine) some immunity from liability, but this does not mean COVID-19 vaccine injuries are not covered or compensated for. They are covered under the Countermeasures Injury Compensation Program (CICP). The PREP Act authorizes CICP to provide benefits to certain individuals or estates of individuals who sustain a covered serious physical injury as the direct result of the administration or use of covered countermeasures identified in and administered or used under the PREP Act declaration.

Although vaccine manufacturers are not liable for unforeseen adverse events, ***they would be liable for negligence.***

For more information on the PREP Act, please see the Public Health Emergency website.

For more information on CICP, please see the HRSA website.

133) "I have heard that COVID-19 vaccines were developed to control the population through microchip tracking. Is this true?"

No. There is no vaccine microchip, and the vaccine will not track people. This myth started after comments made by Bill Gates about a digital certificate of vaccine records. The technology he was referencing is not a microchip, has not been implemented in any manner and is not tied to the development, testing or distribution of COVID-19 vaccines.

134) "I have heard the head of Pfizer research said the vaccine could cause female sterility? Is this true?"

This claim is false. Experts say there is no evidence that the Pfizer vaccine would result in sterilization of women.

If you look into the original claim on social media, you will discover it is full of misinformation.

- First, the person who made the claim is not the head of Pfizer research. **The truth:** the individual worked at Pfizer nearly a decade ago in a division that was not directly involved in vaccinology.
- Second, the claim says the COVID-19 mRNA vaccine produces a protein called syncytin-1, which is vital for placental formation. If the body creates an immune response to syncytin-1, the immune system may inadvertently attack the placenta during future pregnancies and lead to infertility. **The truth:** the vaccine works by forming an immune response to the SARS-CoV-2 spike protein. The SARS-CoV-2 spike protein does share a very small genetic sequence with syncytin-1. However, there is little concern about the possibility of the anti-spike protein antibodies attacking the syncytin-1 protein because the immune system recognizes the surface of target proteins, and this is rarely confined to a short genetic sequence (like the genetic sequence shared between the SARS-CoV-2 spike protein and syncytin-1).
- Finally, if this claim was true, those who have had natural infection with COVID-19 would also produce antibodies to the syncytin-1 protein and would experience infertility. Currently, we have no evidence that natural infection is leading to infertility in women.

135) "I have heard there are new strains of coronavirus circulating worldwide. Will the COVID-19 vaccines provide protection against it?"

It is unknown whether the new virus strains (caused by mutations) will affect the efficacy of vaccines in the long run. Both Pfizer and Moderna have reported that their vaccines produce immune responses that recognize and neutralize variant strains, although there was a reduction in antibodies that neutralize some variants. We also know that the Johnson & Johnson vaccine was 57% effective in clinical trials in South Africa, where one mutant strain is common.

It is possible a variant of the virus may someday make current vaccines ineffective. The manufacturers anticipated potential mutation of the virus, as this is common in coronaviruses. Because of this knowledge, vaccines have been designed to target the entire spike protein on the surface of SARS-CoV-2. Vaccinated individuals produce antibodies that recognize many different parts of the spike protein, so even if one portion of the protein changes or mutates, there will be antibodies to other parts of the protein, which makes it harder for the virus to completely evade our immune systems.

136) "I have heard Norway is reporting deaths in elderly persons getting COVID-19 vaccine. Is the vaccine responsible for these reported deaths?"

Norway has reported 33 elderly patient deaths occurring among those who had received a first dose of Pfizer's COVID-19 vaccine. Health officials in Norway have stated that no link has been established between COVID-19 vaccination and any post-vaccination deaths in the country.

It is important to note that in Norway, an average of 400 people die each week in nursing homes and long-term care facilities, and that the deaths did not represent any excess mortality or causal connection from COVID-19 vaccination. Further, the Norwegian Medicines Agency and the National Institute of Public Health jointly assessed all reports of suspected adverse reactions. They suggest when considering vaccinating frail or terminally ill patients against COVID-19, an evaluation should be undertaken to determine whether the benefits of vaccination outweigh the risks of eventual side effects.

137) "I heard that VAERS has many reports of people who were vaccinated and then died. Is this true?"

While there have been deaths reported to VAERS following COVID-19 vaccination, the CDC has determined that the deaths were not caused by the COVID-19 vaccine. It is important to note that anyone can report to VAERS, and any adverse event following a vaccination is encouraged to be reported so it can be investigated. While these reports may be temporally related (e.g. happened close together) that does not mean they are causally related (e.g. one event caused the other). The fact that we are seeing these events following COVID-19 vaccine being reported through VAERS, shows us that our vaccine safety monitoring system is working.

Whenever a death or any serious event is reported to our monitoring systems following a COVID-19 vaccination they are taken very seriously and thoroughly investigated. Just because a death occurred following vaccination, it does not mean the vaccine caused the event. There are an average of 8,000 deaths every day in the U.S., and with over a million doses of COVID-19 vaccine being administered to the public *daily* in our country, the likelihood of a death occurring in those who have received a vaccine is not unexpected. That does not mean that the death was caused by getting vaccinated against COVID-19. There has been no increase in the rate of death in the vaccinated population in comparison to those who have not received a COVID-19 vaccine. Further, the CDC has not identified a single case in which the vaccine caused a person's death.

138) "Can I still donate blood if I have received a COVID-19 vaccine?"

The FDA guidelines state that individuals that have received an mRNA COVID-19 vaccine (Pfizer & Moderna vaccine) or a nonreplicating COVID-19 vaccine (Johnson & Johnson vaccine) can donate blood without a waiting period between receiving a COVID-19 vaccine and donating blood. The Red Cross and Vitalant have stated that if you have been vaccinated against COVID-19 you can still donate blood. Be prepared to provide the manufacturer name of the COVID-19 vaccine you received when you come to donate blood. Individuals should also consider bringing their Vaccination Record Card to their donation appointment.

139) "Can I still donate convalescent plasma if I have received a COVID-19 vaccine?"

On Jan. 15, the U.S. Food and Drug Administration updated its guidance regarding convalescent plasma donor eligibility for those who receive a COVID-19 vaccine. The new guidance states that individuals who had COVID-19 symptoms and received a confirmed COVID-19 diagnostic test prior to vaccination, have fully recovered from symptoms of the virus within the last six months and meet other donation eligibility criteria may be able to donate convalescent plasma. This is to ensure that COVID-19 convalescent plasma collected from donors contains sufficient antibodies directly related to their immune response to COVID-19 infection.

However, at this time individuals who have received a COVID-19 vaccine are not able to donate convalescent plasma with the Red Cross or Vitalant. Currently, the Red Cross is working as quickly as possible to evaluate this change—as it may involve complex system updates. Please check with your local plasma donation center to see what their guidelines are regarding convalescent plasma donations and COVID-19 vaccine.

140) Are any of the COVID-19 vaccines made with fetal cells?

- The mRNA COVID-19 vaccines produced by Pfizer and Moderna **do not require the use of any fetal cell cultures in order to *manufacture* the vaccine.**
    - The following organizations assert that the mRNA COVID-19 vaccines as ethically uncontroversial: National Catholic Bioethics Center, The Vatican - Congregation for the Doctrine of the Faith, Pontifical Academy of Life Statement, Charlotte

Lozier Institute, United States Conference of Catholic Bishops (USCCB), and the North Dakota Catholic Conference.

- The non-replicating viral vector COVID-19 vaccine made by Johnson & Johnson did require the use of fetal cell cultures to develop and manufacture the vaccine.
    - The Catholic Church and the Southern Baptist Ethics & Religious Liberty Commission have both stated that receiving a COVID-19 vaccine that required fetal cell lines for production or manufacture is morally acceptable.
    - Individuals should not delay vaccination because of product preference.
- For more information on this topic please view the NDDoH handout.

CDC COVID-19 Vaccine Education

The CDC is offering a new, web-on-demand, self-paced module for healthcare providers who will be administering COVID-19 vaccine. The module will cover:

- Information about COVID-19 vaccine Emergency Use Authorization and safety
- General information about vaccine storage, handling, administration, and reporting

For more information on this education see the CDC website.

To access the module, check out the CDC COVID-19 Vaccine Training Module.

Please feel free to contact the NDDoH Immunization Program with any questions or concerns at covidvaccine@nd.gov or 701.328.3386 or toll-free at 800.472.218